Unify™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

MODELS CD3231-40 (DF-1, IS-1) and CD3231-40Q (SJ4)

SPECIFICATIONS

- Advanced Biventricular Pacing options.
  - – VectSelect® programmable LV pulse configuration (LV ring-RV coil, LV tip-RV coil or LV bipolar) may be adjusted noninvasively via the programmer.
  - – Triggered Pacing with BiV Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event.
  - – Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing.
- Unique 40 J Safety Shock option, delivered energy, provides a greater DFT safety margin and may minimize the need for multiple DFT tests at implant.
- The SJ4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.
- QHR® chemistry battery provides greater capacity for enhanced longevity and charge times.
- The addition of antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for converting tachyarrhythmias prior to or while charging.
- The % BiV-Pacing alert notifies clinics when percent biventricular pacing is less than the programmed threshold.
- The Low Frequency Attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves.
- BiVCap®, LVCap™, RVCap® and ACap® Confirm features promote patient safety by automatically ensuring capture of the myocardium in response to pacing stimuli in the left ventricle, right ventricle and right atrium.
- DeFT Response® technology tools provide more clinically proven, noninvasive options for managing high DFTs.
  - – Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.[1]
  - – SVC shocking electrode can be quickly and noninvasively activated or deactivated with the press of a button.
  - – 40 J delivered energy provides unsurpassed energy for defibrillation.
  - – Four programmable tilt options are available to accommodate variances among patients.[2]
- Unique Sense*Ability*® feature, with Decay Delay and Threshold Start, provides the flexibility to fine-tune sensing to individual patient needs.
- QuickOpt® timing cycle optimization provides quick and effective optimization for more patients at the push of a button.[3]
- Unique Morphology Discrimination plus AV Rate Branch SVT discrimination feature helps reduce the risk of inappropriate ICD shocks and is intended to promote fast, accurate diagnosis and delivery of therapy. Clinical data states that this combination resulted in a sensitivity of 100% with a specificity of 85%.[4]
- Unique AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
  - – Studies show a 25% decrease in symptomatic AF burden.[5]
- AT/AF Alerts notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode.
- Up to 45 minutes of continuous, fully annotated stored electrograms, including up to 60 seconds of pre-trigger information per electrogram.
- Unique Vibratory Patient Notifier allows even patients with hearing problems to be alerted to a low battery, lead-related complications and more.
- Automatic Daily High-Voltage (HV) Lead Integrity Test is designed to automatically test the HV lead on a daily basis to ensure therapy delivery for optimal patient safety.
- Multiple hardware and software system safeguards are included for added security and patient comfort.
- Decreased device footprint and volume with the most narrow (40 mm) design.

Indications and Usage:
Unify pulse generators are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. AF Suppression pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction. In patients indicated for an ICD, Unify pulse generators are also intended to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section included in the Merlin® Patient Care System [PCS] on-screen help) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration; to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.

Contraindications:
Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Warnings and Precautions:
Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
Lead System. Do not use another manufacturer's lead system without demonstrated compatibility as undersensing cardiac activity and failure to deliver necessary therapy may result.
Avoiding Shock During Handling. Disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-mortem procedures as well as when disconnecting leads as the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.
Additional Pacemaker Implanted. These devices provide bradycardia pacing. If another pacemaker is used, it should have a bipolar pacing reset mode and be programmed for bipolar pacing to minimize the possibility of the output pulses being detected by the device.
Modifying the Device. This device has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by St. Jude Medical Inc. could void the user's authority to operate this device.
Suboptimal Radio Frequency (RF) Communication. The Merlin PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the Merlin PCS and the Merlin Antenna. Please see the User's Manual for a list of potential causes to suboptimal radio communication.

Potential Adverse Events:
Possible adverse events (in alphabetical order) associated with the system, include, but are not limited to the following: acceleration of arrhythmias (caused by device), air embolism, allergic reaction, bleeding, cardiac tamponade, chronic nerve damage, death, erosion, exacerbation of heart failure, excessive fibrotic tissue growth, extracardiac stimulation (phrenic nerve, diaphragm, chest wall), extrusion, fluid accumulation, formation of hematomas or cysts, inappropriate shocks, infection, keloid formation, lead abrasion and discontinuity, lead migration/dislodgment, myocardial damage, pneumothorax, shunting current or insulating myocardium during defibrillation with internal, or external paddles, potential mortality due to inability to defibrillate or pace, thromboemboli, venous occlusion, venous or cardiac perforation. Patients susceptible to frequent shocks despite antiarrhythmic medical management, may develop psychological intolerance to an ICD or CRT-D system that may include the following: dependency, depression, fear of premature battery depletion, fear of shocking while conscious, fear of losing shock capability, imagined shocking (phantom shock).

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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MORE CONTROL. LESS RISK.

PHYSICAL SPECIFICATIONS

Models	CD3231-40	CD3231-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	36	36
Weight (g)	78	77
Size (mm)	79 x 40 x 14	73 x 40 x 14
Defibrillation Lead Connections	DF-1	SJ4
Sense/Pace Lead Connections	IS-1	SJ4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETERS	Settings
Biventricular Pacing	
V. Triggering (BiV Trigger Mode)	On; Off
QuickOpt® Timing Cycle Optimization	Sensed/paced AV delay; interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
VectSelect® LV Pulse Configuration	LV tip to RV coil; LV bipolar; LV ring to RV coil
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 ppm
Sensing/Detection	
Sense*Ability*® Technology	Automatic Sensitivity Control adjustment for atrial ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62.5; 75; 100%; (Post-Paced; Atrial) 0.2-3.0 mV; (Post-Sensed; Ventricular) 50; 62.5; 75; 100%; (Post-Paced; Ventricular) Auto; 0.2-3.0 mV
Decay Delay	(Post-Sensed/Post-Paced; Atrial/Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	VT-1; VT-2; VF
SVT Discriminators	AV Rate Branch; Sudden Onset; Interval Stability; Morphology Discrimination (MD) with Manual or Automatic Template Update
Reconfirmation	Continuous sensing during charging
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150-300 bpm
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts	1-15
Number of Stimuli	2-20
Add Stimuli per Burst	On; Off
High-Voltage Therapy	
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can

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*LV first with 10 ms interventricular delay.

Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (ppm); Rest Rate (ppm); Maximum Tracking Rate (ppm) Maximum Sensor Rate (ppm); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (ppm); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate	110-300
AMS Base Rate	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace on PMT; Off; Passive
Rate Responsive	PVARP/VREF Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP®)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
LVCap™ Confirm, RVCap® Confirm	Setup; On; Monitor; Off
ACap® Confirm	On; Monitor; Off
Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI; DDI; DDD; AAI
Post-Shock Base Rate (ppm)	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0.5; 1; 2.5; 5; 7.5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0.5-5.0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to 3 extrastimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; Long AT/AF Episode
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostic	
Stored Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verification
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes

1. Mouchawar G, Kroll M, Val-Mejias JE et al. ICD waveform optimization: a randomized prospective, pair-sampled multicenter study. *PACE* 2000;23(Part II):1992-1995.
2. Sweeney MO, Natale A, Volosin KJ et al. Prospective randomized comparison of 50%/50% versus 65%/65% tilt biphasic waveform on defibrillation in humans. *PACE* 2001;24:60-65.
3. Baker JH, Mckenzie J, Beau S et al. Acute evaluation of programmer-guided AV/PV and VV delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. Journal of Cardiovascular Electrophysiology 2007;18:185-191.
4. Sperzel J, Meine M et al. A new automatic update function of the morphology template used for SVT/VT discrimination in an ICD. Europace Supplements 2002;3:A131, #1515.
5. Carlson MD et al. A new pacemaker algorithm for the treatment of atrial fibrillation: results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). *JACC* 2003;42:627-633.

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Unless otherwise noted, ® or ™ indicates a registered or unregistered trademark or service mark owned by, or licensed to, St. Jude Medical, Inc. or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2010 St. Jude Medical, Inc. All rights reserved. Item No.G0318